FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Meeting of the Drug Safety and Risk Management Advisory Committee

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Room 1503), 10903 New Hampshire Avenue, Silver Spring, MD

January 24-25, 2013

DRAFT QUESTIONS

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1. **(DISCUSSION)** Please discuss what the pharmacology data and the epidemiology data suggest about the potential for abuse of hydrocodone combination products compared with drugs that are currently in schedule II.

2. **(DISCUSSION)** Please discuss what impact rescheduling of hydrocodone combination products from schedule III to II would have on the following:
   a. Prescribing patterns for opioids, including hydrocodone combination products.
   b. Delivery of healthcare in the US, including impacts on drug distribution, manufacturing, prescription and dispensing by pharmacies.
   c. Availability of hydrocodone combination products for patients with appropriate needs for them as well as by individuals seeking to abuse opioids.
   d. Abuse and misuse of opioids, especially hydrocodone combination products.

3. **(DISCUSSION)** Please discuss whether there are other activities that could reduce abuse and misuse of these products?

4. **(VOTING)** Based on the background materials, presentations and the discussion above, do you recommend that hydrocodone combination products be rescheduled from schedule III to schedule II of the Controlled Substances Act (CSA)? Please explain the basis for your vote.